U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program

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October 24, 2007

Dr. Joan Gotthardt
Director, Division of Therapeutic Drugs
for Food Animals
Document Control Unit, HFV – 199
Center for Veterinary Medicine
7500 Standish Place, MPN-2
Rockville, MD 20855

Dear Dr. Gotthardt:

The purpose of this submission is to provide the U. S. Food and Drug Administration's Center for Veterinary Medicine with a proposed temperature classification system for the systematic (and defensible) "grouping" of publicly cultured finfish into four major categories. As proposed, the four major categories would include: 1) coldwater species; 2) coolwater species; 3) warmwater species; and 4) coolwater/warmwater "crossover" species. The proposed classification system is based on the most common rearing water temperature range for each category.

The need for such a classification system was identified by CVM's Aquaculture Drugs Team, through the Association of Fish and Wildlife Agencies' Drug Approval Working Group, as a tool that would facilitate addressing potential questions surrounding the recent approval of 35% PEROX-AID® for use to control mortality in all freshwater, *coolwater* finfish caused by external columnaris, and more specifically, address issues related to whether labeled or off-label use is warranted for specific fish species (i.e., "…what species does CVM consider to be a coolwater species?". It is anticipated that the proposed classification system would also have pre- and post-approval application for other aquatic animal drugs. Please note that the enclosed classification system was generated in-part through efforts of the National Aquaculture Drug Research Forum, a subgroup of the Joint Subcommittee on Aquaculture's Working Group on Drugs,

Biologics, and Pesticides. Also please note that we request that CVM formally review the enclosed proposed temperature classification system and develop an opinion with respect to its applicability to: 1) existing approvals (e.g. 35% PEROX-AID®); and 2) data development requirements for future approvals. Because information contained in this request is applicable to virtually all Service-held INADs, we suggest that it be coded as General Correspondence.

Assembly of the proposed temperature classification system was based on information extracted from the 2005 Public Aquaculture Production Database (PAPD) which is available at the AADAP website at: http://www.fws.gov/fisheries/aadap/Aqua%20Production%20Data%20Intro.htm. While we acknowledge that the 2005 PAPD may not provide the most definitive data available with respect to the potential temperature classification of finfish, it does provide an accurate, comprehensive, up-to-date, and standardized listing of finfish reared domestically by public sector agencies.

Although it is fully expected that CVM's Aquaculture Drugs Team may find the proposed temperature classification system incomplete and/or otherwise lacking, it is certainly our hope that the enclosed material provides a framework from which we can mutually move forward to more definitively group fish species. Please note that in the future AADAP (with assistance from the NADRF and CVM) will continue our efforts to more clearly define fish species classification based on additional parameters (e.g., preferred optimal rearing temperature, spawning temperature, etc.) and/or best available information.

The current sponsor of all Service-held INADs is Dr. David Erdahl, Branch Chief, U.S. Fish and Wildlife Service – AADAP Program, 4050 Bridger Canyon Road, Bozeman, MT 59715. We would like to thank you in advance for your time and consideration with respect to the above-described request. If you have questions, please contact Dr. Erdahl at (406) 994-9904.

Sincerely,

Dr. David Erdahl
AADAP Program – Branch Chief

Enclosures: A Proposed Classification System for Finfish Based on Rearing Temperature (3 copies)

Appendix 1: Excerpt of Fish Production, Water Type, and Temperature Information from the 2005 Public Aquaculture Production Database (3 copies)